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MAY 3 1 2006

510(K) SUMMARY
SMITH & NEPHEW REFLECTION 3 ACETABULAR SYSTEM

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-5778
CONTACT PERSON:	Katie Logerot
DATE SUMMARY PREPARED:	May 2, 2006
TRADE OR PROPRIETARY DEVICE NAME:	REFLECTION 3 Acetabular System
COMMON OR USUAL NAME:	Hip Stem
CLASSIFICATION NAME:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis – Class II
DEVICE CLASS:	Class II
PRODUCT CODE:	Orthopedics/87/MBL

DEVICE INFORMATION:

A. INTENDED USE:

The REFLECTION 3 Acetabular System is indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease.(NIDJD) or any of its composite diagnoses such as osteoarthritis; avasular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; non-union; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy; or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The REFLECTION 3 Acetabular System is for single use only. The REFLECTION 3 Acetabular System is intended for cementless use.

B. DEVICE DESCRIPTION:

The REFLECTION 3 Acetabular System consists of acetabular shells and liners. The REFLECTION 3 Shells are manufactured from titanium alloy. The REFLECTION 3 liners are manufactured from XLPE. The design of the shells and liners are similar to the REFLECTION Acetabular Shell, the REFLECTION Interfit Shell, and the 10MRad REFLECTION Acetabular Liner.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The substantial equivalence of the REFLECTION 3 Acetabular System is supported by its similarities in design features, overall indications, and material composition to the RELFECTION Acetabular System (K920430, K932755, K990666), the REFLECTION Interfit Shell (K9640094, K990666), and the 10MRad REFLECTION Acetabular Liner (K002747) manufactured and distributed by Smith & Nephew, Inc.

D. **SUMMARY OF TECHNOLOGICAL COMPARISON:**

The intended use, design, and materials of the REFLECTION 3 Acetabular System are substantially equivalent to the RELFECTION Acetabular System (K920430, K932755, K990666), the REFLECTION Interfit Shell (K9640094, K990666), and the 10MRad REFLECTION Acetabular Liner (K002747). Design Control Activities have been completed and the results indicate that the subject device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2006

Smith & Nephew, Inc.
c/o Ms. Katie Logerot
Regulatory Affairs Specialist II
Orthopedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K061253
Trade/Device Name: REFLECTION 3 Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBL
Dated: May 3, 2006
Received: May 4, 2006

Dear Ms. Logerot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061253

Indications for Use

510(k) Number (if known): K061253

Device Name: REFLECTION 3 Acetabular System

Indications for Use:

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The REFLECTION 3 Acetabular System is for single use only. The REFLECTION 3 Acetabular System is intended for cementless use.

Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061253